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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,556	09/29/2004	Alain Delval	930024-2013	5915
<div>7590 08/28/2007</div> <div>Ronald R Santucci Frommer Lawrence & Haug 745 Fifth Avenue New York, NY 10151</div>				
			EXAMINER WILSON, JOHN J	
			ART UNIT 3732	PAPER NUMBER
			MAIL DATE 08/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.

10/509,556

Applicant(s)

DELVAL ET AL.

Examiner

John J. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7 and 11 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. The rotation of the tool as disclosed would also rotate the tool at the bend. This would cause the bent portion of the tool to crimp, fatigue and break, and/or create such forces on the pivot elements 28, 29, 32 so as to render them inoperable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rotation of the tool as disclosed would also rotate the tool at the bend. This would cause the bent portion of the tool to crimp, fatigue and break, and/or create such forces on the pivot elements 28, 29, 32 so as to render them inoperable. The disclosure does not teach materials that can be used to make the tool and/or pivot

elements that would not destruct in use. Determining these materials or determining how to rotate the tool without destroying the holder is more than routine investigation for one of ordinary skill in the art, and therefore, claims to this embodiment are not enabled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cislak (1993398). Cislak shows a tool holder having an elongated body 13, channel 15, 16, cylindrical part of the channel 15 and widened part of the channel 16, means 22 for keeping a tool in position, and as shown, a generatrix of the widened channel 16 is parallel to the axis of the cylindrical part 15. The shown means for keeping the tool in position is inherently capable of keeping a tool with an axis not parallel to the axis of the body, for example, the claimed structure could keep a bent tool in position. The intended use of this shown structure with an inferentially claimed flexible deformable tool is not given any patentable weight. The specific manner in which the shown structure may interact with the inferentially claimed tool in use is held to be an obvious matter of choice in the use of a known structure. As to claims 4-6, the type of connection used is an obvious matter of choice in well known connecting means to one of ordinary skill in the art. As to claim 8, the shown tool is inherently flexible and

deformable to some degree. The shown elements that are intended to mate with the inferentially claimed tool are capable of allowing rotation.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cislak (1993398) as applied to claim 9 above, and further in view of Gibbs (6468248). Cislak shows the structure as described above, however, does not show means for rotation of the tool. Gibbs teaches means for rotating a tool, Fig. 7A. It would be obvious to one of ordinary skill in the art to modify Cislak to include rotation means as shown by Gibbs in order to cut material when desired.

Response to Arguments

Applicant's arguments filed June 18, 2007 have been fully considered but they are not persuasive. Applicant argues, with respect to the 35 U.S.C. 101 rejection, that the tool is both flexible and deformable, and therefore, can rotate. The rejection is not based on the tool not being able to rotate, instead, it is based on the tool self destructing when driven to rotate because of the forces applied. If the tool were so flimsy that it can be driven to rotate without fatiguing, it would not be capable of operating as disclosed as a injection needle or cutting tool. With respect to the rejection under 35 U.S.C. 112, first paragraph, applicant cites prior art, 4,512,769 and 6,162,202 to show that materials that are flexible and deformable are known stating that they can be rotated without fatiguing/breaking at the bend, however, these references do not teach that they are capable of being driven in rotation, instead, they merely show the ability to conform to a

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curved canal. As such, they do not show that such materials are well known to one of ordinary skill in the art. With respect to applicant's arguments that the factors of *In re Wands* has not been demonstrated, it is held that the lack of disclosure as to direction, guidance or nature of the invention is obvious from reading the disclosure, and that, the nature of fatigue with respect to materials capable of functioning as an injection needle or cutting tool are well known and obvious in general and in specific to one of ordinary skill in the art. With respect to the rejection under 35 U.S.C. 103(a), because the tool is only inferentially claimed, "intended to receive a flexibly deformable tool", claim 1, lines 1 and 2, it is not necessary to show a tool with an axis not parallel to the axis of the body, it is only necessary to show a tool holder that is capable of holding such a tool. The shown structure is inherently capable of holding a bent tool, for example, the bent steel needle 80 shown in the art cited by applicant, 4,512,769. With respect to the limitation "of which one of the generatrices being substantially parallel to the axis", claim 1, this limitation is as broad as there exists a plurality of lines that can generate a surface. That a parallel line can generate the surface shown in the prior art is inherent in the shown shape.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John J. Wilson whose telephone number is 571-272-4722. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez, can be reached at 571-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

***/John J Wilson/
Primary Examiner
Art Unit 3732***

jw
August 25, 2007